

AUG 1 - 2005

K050927

Fisher & Paykel Healthcare Limited
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Auckland, New Zealand
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1.4 510(k) Summary of Safety and Effectiveness

Contact person Reneta Money

Date prepared 30 March 2005

Trade name RT019 Inspiratory/Expiratory Filter

Common name Breathing Circuit Bacterial Filter

Classification name Breathing Circuit Bacterial Filter (21 CFR 868.5260)

Predicate device RT020 End Expiratory Filter K002839

1.4.1 Description of device

The Fisher & Paykel Healthcare RT019 Inspiratory/Expiratory Filter is classified as a 'Breathing Circuit Bacterial Filter' according to 21 CFR §868.5260. It is intended to be placed at the machine end of a ventilator breathing circuit, to remove microbiological and particulate matter from the gases in a breathing circuit.

The RT019 filter has a dual-walled translucent thermoplastic enclosure with aligned connector ports and perpendicular filter media. Its total length is 78 mm (3.1 in) with a maximum cross section diameter of 67 mm (2.6 in), and a mass of 23 g (0.81 oz). It has standard 22 mm male and female connector ports with 1:40 conical tapers. The filter uses an electrostatic, hydrophobic, depth-type filter media.

1.4.2 Intended use

The Fisher & Paykel Healthcare RT019 Inspiratory/Expiratory Filter is intended for use between a ventilator and a breathing circuit. Its function is to remove microbiological and particulate matter from gases entering and/or exiting a breathing circuit. The RT019 is intended to be connected to the ventilator inspiratory and/or expiratory ports. It is not directional in terms of flow and is a single use device.

1.4.3 Technological characteristics summary

As the RT019 is identical to the predicate device in every physical aspect, it shares the same technological characteristics.

1.4.4 Summary of testing:

No additional tests were performed on the RT019 filter as it is identical to the predicate device (RT020). A change in the indications for use does not affect the filter's safety, efficacy or performance.

1.4.5 Conclusions demonstrating safety, effectiveness and performance

The Fisher & Paykel Healthcare RT019 Inspiratory/Expiratory Filter is identical to the predicate device in every aspect including safety, effectiveness and performance.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Fisher & Paykel Healthcare, Limited
c/o Reneta Money
15 Maurice Paykel Place
P.O. Box 14-348, Panmure
East Tamaki, Auckland
NEW ZEALAND

Re: K050927

Trade/Device Name: RT019 Inspiratory/Expiratory Filter
Regulation Number: 21 CFR 868.5260
Regulation Name: Breathing Circuit Bacterial Filter
Regulatory Class: II
Product Code: CAH
Dated: July 18, 2005
Received: July 21, 2005

Dear Ms. Money:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Chiu Lin', with a stylized flourish at the end.

Chiu Lin, Ph.D.,

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

1.2 Indications for Use Statement

510(k) Number: 16050927

Device Name: RT019 Inspiratory/Expiratory Filter

Indications For Use: The Fisher & Paykel Healthcare RT019 Inspiratory/Expiratory Filter is intended for use between a ventilator and a breathing circuit. Its function is to remove microbiological and particulate matter from gases entering and/or exiting a breathing circuit. The RT019 is intended to be connected to the ventilator inspiratory and/or expiratory ports. It is not directional in terms of flow and is a single use device.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Amir Sulaiman K050927
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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